



PROGRAM MATERIALS

Program #30292

December 21, 2020

COVID-19: Vaccination Protocols and the Regulatory and Legal Landscape

Copyright ©2020 by:

- **Andrea Kirshenbaum, Esq. - Post & Schell P.C.**
- **Elizabeth Hein, Esq. - Post & Schell P.C.**

All Rights Reserved.

Licensed to Celesq®, Inc.

Celesq® AttorneysEd Center

www.celesq.com

5255 North Federal Highway, Suite 310, Boca Raton, FL 33487

Phone 561-241-1919

Fax 561-241-1969

COVID-19: Vaccination Protocols and the Regulatory and Legal Landscape

December 21, 2020

Andrea M. Kirshenbaum

Chair, Wage and Hour Practice Group
Principal, Employment and Employee
Relations Practice Group
Member, COVID-19 Taskforce
Post & Schell, P.C.

Elizabeth M. Hein

Associate
Health Care Practice Group
Member, COVID-19 Taskforce
Post & Schell, P.C.

Andrea M. Kirshenbaum

Chair, Wage and Hour Practice Group
Principal, Employment and Employee Relations Practice Group
Member, COVID-19 Taskforce
Post & Schell, P.C.

akirshenbaum@postschell.com
(215) 587-1126



Elizabeth M. Hein

Associate, Health Care Practice Group
Member, COVID-19 Taskforce
Post & Schell, P.C.

ehhein@postschell.com
(215) 587-1075



COVID-19 Vaccines: Current Status

- As the time of this presentation, the FDA has approved two COVID-19 vaccines for Emergency Use Authorization.
 - Pfizer and BioNTech's COVID-19 vaccine was approved on December 11, 2020.
 - Moderna's COVID-19 vaccine was approved on December 18, 2020.
- Pfizer and BioNTech's COVID-19 vaccine is in the early stages of distribution and has already been given to healthcare workers and long-and term care facility residents.
- A number of high-profile individuals have publicly received the vaccine, or plan to, in order to bolster public confidence, including Vice President Pence and President-Elect Biden.



Vaccine vs. Vaccination

- Will Americans voluntarily get vaccinated?
 - A November 2020 Gallup Poll showed **58%** of Americans said they would get a COVID-19 vaccine.*
 - A December 2020 Pew Research Poll showed that **60%** of Americans said, “they would definitely or probably get a vaccine for the coronavirus.” **



* <https://news.gallup.com/poll/325208/americans-willing-covid-vaccine.aspx>

** <https://www.pewresearch.org/science/2020/12/03/intent-to-get-a-covid-19-vaccine-rises-to-60-as-confidence-in-research-and-development-process-increases/>

So what is an employer to do?

- Follow a “flu vaccine approach” (for non-healthcare employers)
 - Offer free to employees on a voluntary basis or encourage employees to get the vaccine (with or without reimbursement).
- Create a hybrid approach
 - Mandate the COVID-19 vaccine for certain categories of workers (for example those who cannot work remotely or cannot fully social distance).
 - Must have an exemption process for religion and disability.
- Mandate the COVID-19 vaccine for all employees (with an exemption process)



Lessons Learned in the Flu Vaccine Trenches

- Employers looking to put in place a COVID-19 vaccine protocol need look no further than to caselaw and guidance developed over the past several years following the decision by many healthcare providers put in place mandatory flu vaccine protocols for their employees (with exemptions available for religion and disability).
- Now is the time to put in place and implement a COVID-19 vaccine protocol.



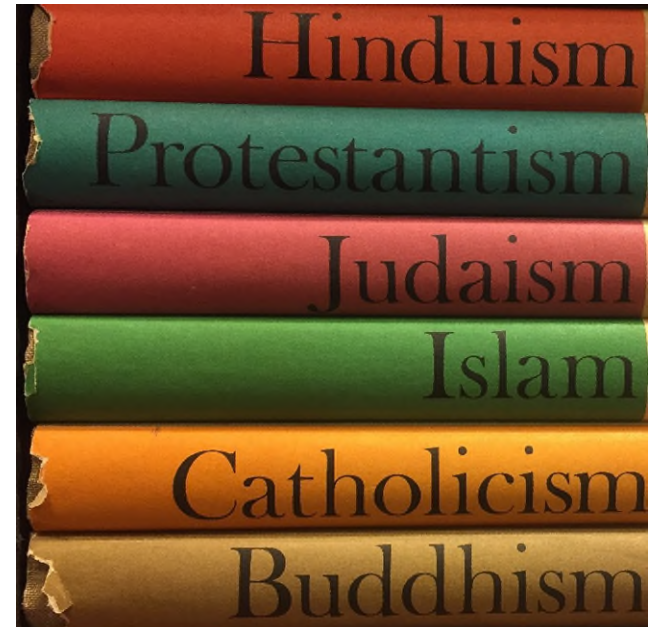
Lessons Learned in the Flu Vaccine Trenches

- ✓ Create an exemption policy and process.
- ✓ Identify who will decide exemption requests.
- ✓ Educate the decisionmakers as to what process to use.
- ✓ Roll out the process to employees.
- ✓ Make decisions and convey them to employees so that when the vaccine is available you are ready to go.



Religious Exemption

- Title VII (and the Pennsylvania Human Relations Act or other similar state law):
 - Prohibits discrimination “because of . . . religion.”
 - Requires reasonable accommodation.
 - Religion includes “all aspects of religious observance and practice, as well as belief, unless an employer demonstrates that he is unable to reasonably accommodate to an employee’s or prospective employee’s religious observance or practice without undue hardship on the conduct of the employer’s business.”
- “Undue hardship” under Title VII if employer can demonstrate the accommodation would require “more than a *de minimis* cost.”



Third Circuit Flu Vaccination Case – 877 F.3d 487 (3d Cir. 2017)

- In 2012, the Hospital began requiring employee flu vaccinations.
- Employees seeking exemption needed to fill out a form.
- Fallon, an employee since 1994, submitted requests for exemption in 2012 and 2013 outlining his “sincerely held beliefs” regarding the harmfulness of vaccines.
- The Hospital approved the exemption requests in both years.



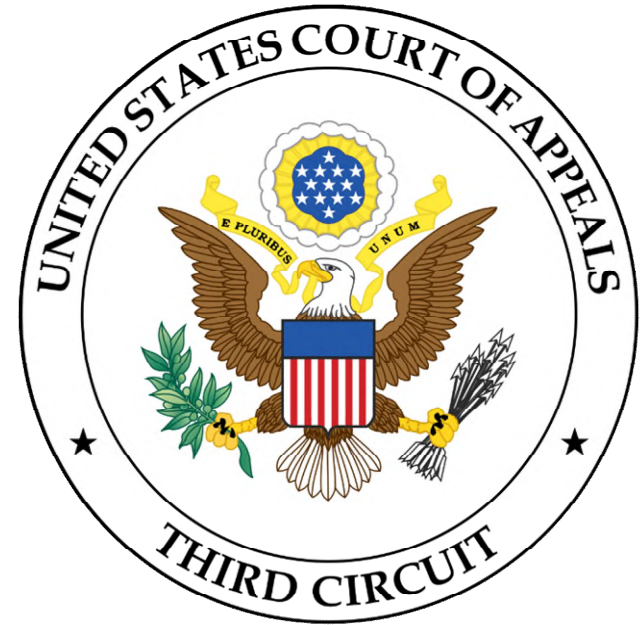
Third Circuit Flu Vaccination Case – 877 F.3d 487 (3d Cir. 2017)

- In 2014, after evaluating his request and detailed essay setting out his religious beliefs, the Hospital denied Fallon's request, citing changes in its standards for exemption.
- The Hospital requested a letter from a clergyperson supporting Fallon's requested exemption which he was not able to provide because he did not belong to any religious organization.
- He was subsequently terminated and filed suit alleging religious discrimination and failure to accommodate his religion (as well as wrongful termination in violation of public policy).



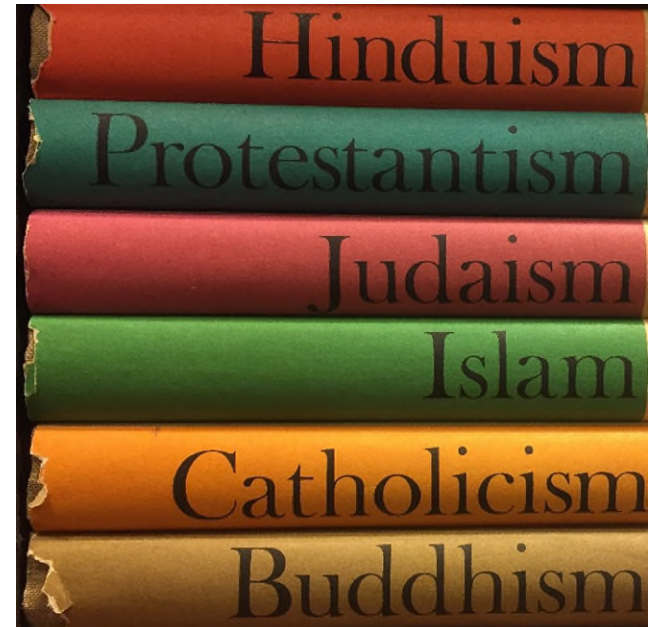
Third Circuit Flu Vaccination Case – 877 F.3d 487 (3d Cir. 2017)

- The Hospital's Motion to Dismiss was granted by the E.D. Pa. and Fallon appealed to the Third Circuit, which examined whether Fallon's beliefs, as articulated in his Complaint and the exemption form and essay he submitted to the Hospital, were religious under Title VII.



Third Circuit Flu Vaccination Case – 877 F.3d 487 (3d Cir. 2017)

- The Third Circuit set out a 3-part test to determine whether the alleged beliefs are religious and therefore protected by Title VII:
 1. A religion addresses **fundamental and ultimate questions** having to do with deep and imponderable matters.
 2. A religion is **comprehensive** in nature; it consists of a belief system as opposed to an isolated teaching.
 3. A religion often can be recognized by the presence of certain **formal and external signs**.



Third Circuit Flu Vaccination Case – 877 F.3d 487 (3d Cir. 2017)

1. His beliefs did not address fundamental and ultimate questions having to do with deep and imponderable matters:
 - **“Generally he simply worries about the health effects of the flu vaccine, disbelieves the scientifically accepted view that it is harmless to most people, and wishes to avoid the vaccine.”**
2. His beliefs were not comprehensive in nature:
 - **He applies one general moral commandment “one should not harm their [sic] own body” which is an “isolated moral teaching” and “not a comprehensive system of beliefs about fundamental or ultimate matters.”**
3. There were no formal or external signs:
 - **His views were not manifested in signs such as “formal services, ceremonial functions, the existence of clergy, structure and organization, efforts at propagation, observation of holidays and other similar manifestations associated with the traditional religions.”**

Third Circuit Flu Vaccination Case – 877 F.3d 487 (3d Cir. 2017)

- Certain anti-vaccination beliefs are not religious.
- However, if anti-vaccination beliefs are a part of a broader religious faith, they are protected.
 - Example given - Christian Scientists who “regularly qualify for exemptions from vaccination requirements.”
- Religious beliefs can be demonstrated in various ways.



EEOC Guidance

- “In most cases whether or not a practice or belief is religious is not at issue. However in those cases in which the issue does exist, the Commission will define religious practices **to include moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views.** This standard was developed in *United States v. Seeger*, 380 U.S. 163 (1965) and *Welsh v. United States*, 398 U.S. 333 (1970)” (emphasis added).
- “The Commission has consistently applied this standard in its decisions. **The fact that no religious group espouses such beliefs or the fact that the religious group to which the individual professes to belong may not accept such belief will not determine whether the belief is a religious belief of the employee or prospective employee.**”

EEOC Guidance

- *U.S. v. Seeger*, 380 U.S. 163 (1965) (and *Welsh v. U.S.*) - Cases involving conscientious objection under § 6(j) of the Universal Military Training and Service Act. Individuals were imprisoned because of failure to serve in the military.
 - That Act exempts from combatant training and service in the armed forces of the United States those persons who by reason of their religious training and belief are conscientiously opposed to participation in war in any form.
 - Religious training and belief: defined as **“an individual’s belief in relation to a Supreme Being involving duties superior to those arising from any human relation, but [not including] essentially political, sociological, or philosophical views or a merely personal moral code”** (emphasis added).
 - Narrow question before the Court was “[d]oes the term ‘Supreme Being’ as used in § 6(j) mean the orthodox G-d or the broader concept of a power or being, or a faith, ‘to which all else is subordinate or upon which all else is ultimately dependent.’”

EEOC Guidance

- The Supreme Court held that “within [the] phrase” “a conviction based upon religious training and belief” **“would come all sincere religious beliefs which are based upon a power or being, or upon a faith, to which all else is subordinate or upon which all else is ultimately dependent”** (emphasis added)
- The test might be stated in these words: **“A sincere and meaningful belief which occupies in the life of its possessor a place parallel to that filled by the G-d of those admittedly qualified for the exemption comes within the statutory definition.”**
 - This holding embraced a broader, non-theistic formulation of “religious training and belief.”



EEOC Guidance

- The EEOC Compliance Manual states that “beliefs are not protected merely because they are strongly held. Rather, **religion typically concerns ‘ultimate ideas’ about ‘life, purpose, and death.’ Social, political, or economic philosophies, as well as mere personal preferences, are not ‘religious’ beliefs protected by Title VII.**” Compliance Manual at 12-I, A, 1.
- EEOC Informal Discussion Letter dated March 5, 2012:
 - **“It is unlikely that ‘religious’ beliefs would be held to incorporate secular philosophical opposition to vaccination.”**
www.eeoc.gov/eeoc/foia/letters/religious_accommodation.html
 - “Facts relevant to undue hardship . . . would presumably include, among other things, **the assessment of the public risk posed at a particular time, the availability of effective alternative means of infection control, and potentially the number of employees who actually request accommodation.**” (emphasis added).

Pandemic Preparedness in the Workplace and the Americans with Disabilities Act

- Issued in 2009 during the H1N1 virus and updated on March 21, 2020 in response to the COVID-19 pandemic (with an explicit statement that employers should follow CDC guidance).

13. May an employer covered by the ADA and Title VII of the Civil Rights Act of 1964 compel all of its employees to take the influenza vaccine regardless of their medical conditions or their religious beliefs?

No. An employee may be entitled to an exemption from a mandatory vaccination requirement based on an ADA disability that prevents her/him from taking the influenza vaccine. This would be a reasonable accommodation barring undue hardship (significant difficulty or expense).

Pandemic Preparedness in the Workplace and the Americans with Disabilities Act (continued)

“Similarly, under Title VII of the Civil Rights Act of 1964, once an employer receives notice that an employee’s sincerely held religious belief, practice, or observance prevents him from taking the influenza vaccine, the employer must provide a reasonable accommodation unless it would pose an undue hardship as defined by Title VII (‘more than a de minimis cost’ to the operation of the employer’s business, which is a lower standard than under the ADA). **Generally, ADA-covered employers should consider simply encouraging employees to get the influenza vaccine rather than requiring them to take it.**”

What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEOC Laws

Where can employers learn more about Emergency Use Authorizations (EUA) of COVID-19 vaccines?

- Some COVID-19 vaccines may only be available to the public for the foreseeable future under EUA granted by the FDA, which is different than approval under FDA vaccine licensure. The FDA has an obligation to:
[E]nsure that recipients of the vaccine under an EUA are informed, to the extent practicable under the applicable circumstances, that FDA has authorized the emergency use of the vaccine, of the known and potential benefits and risks, the extent to which such benefits and risks are unknown, that they have the option to accept or refuse the vaccine, and of any available alternatives to the product.
- The FDA says that this information is typically conveyed in a patient fact sheet that is provided at the time of the vaccine administration and that it posts the fact sheets on its website. More information about EUA vaccines is available on the FDA's EUA page.

What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEOC Laws

If an employer requires vaccinations when they are available, how should it respond to an employee who indicates that he or she is unable to receive a COVID-19 vaccination because of a disability?

- The ADA allows an employer to have a qualification standard that includes “a requirement that an individual shall not pose a direct threat to the health or safety of individuals in the workplace.”
 - However, if a safety-based qualification standard, such as a vaccination requirement, screens out or tends to screen out an individual with a disability, the employer must show that an unvaccinated employee would pose a direct threat due to a “significant risk of substantial harm to the health or safety of the individual or others that cannot be eliminated or reduced by reasonable accommodation.” 29 C.F.R. 1630.2(r).
- Employers should conduct an individualized assessment of four factors in determining whether a direct threat exists: the duration of the risk; the nature and severity of the potential harm; the likelihood that the potential harm will occur; and the imminence of the potential harm.

What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEOC Laws

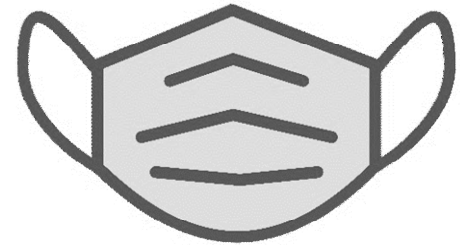
- A conclusion that there is a direct threat would include a determination that an unvaccinated individual will expose others to the virus at the worksite.
 - If an employer determines that an individual who cannot be vaccinated due to disability poses a direct threat at the worksite, the employer cannot exclude the employee from the workplace—or take any other action—unless there is no way to provide a reasonable accommodation (absent undue hardship) that would eliminate or reduce this risk so the unvaccinated employee does not pose a direct threat.
- If there is a direct threat that cannot be reduced to an acceptable level, the employer can exclude the employee from physically entering the workplace, but this does not mean the employer may automatically terminate the worker.
 - Employers will need to determine if any other rights apply under the EEO laws or other federal, state, and local authorities.
 - For example, if an employer excludes an employee based on an inability to accommodate a request to be exempt from a vaccination requirement, the employee may be entitled to accommodations such as performing the current position remotely.

Key Takeaways

- Employees do not need to belong to an organized religion to be exempt from vaccination.
- Employers can ask employees to explain their religious beliefs in order to assess whether to approve a religious exemption.
- Employers cannot require a clergy letter in order to consider an exemption request.
- Both theistic and non-theistic beliefs can qualify as religious.

If the beliefs qualify as religious, then what?

- Consider reasonable accommodation.
 - Let the science and the dictates of the particular workplace and the particular employee situation guide you.
 - Is a mask a reasonable accommodation?
 - Is remote work a reasonable accommodation?
 - Is a transfer into an open position where the employee does not work in close proximity to others a reasonable accommodation?
 - Is a leave of absence a reasonable accommodation?



Other Considerations

- Staffing challenges if the vaccine is mandated
- Pandemic-related financial challenges
- Employee morale
- The obligation to maintain a safe workplace
- Be ready to address potential disability-related exemption requests.
 - Will depend on the components of the particular vaccines and medical contraindications.

NY CLE Credit

- In order to comply with NY regulations, attorneys looking for CLE credit in NY will need to be able to provide a code. This code is not intended for the West LegalEdcenter audience either live or on-demand.
- I will read this code twice and only twice and cannot repeat it or email it to you, so please make note of it.
- The NY State code number is **HK30292-122120**, again, the NY state code number is **HK30292-122120**.

COVID-19 Vaccine Distribution

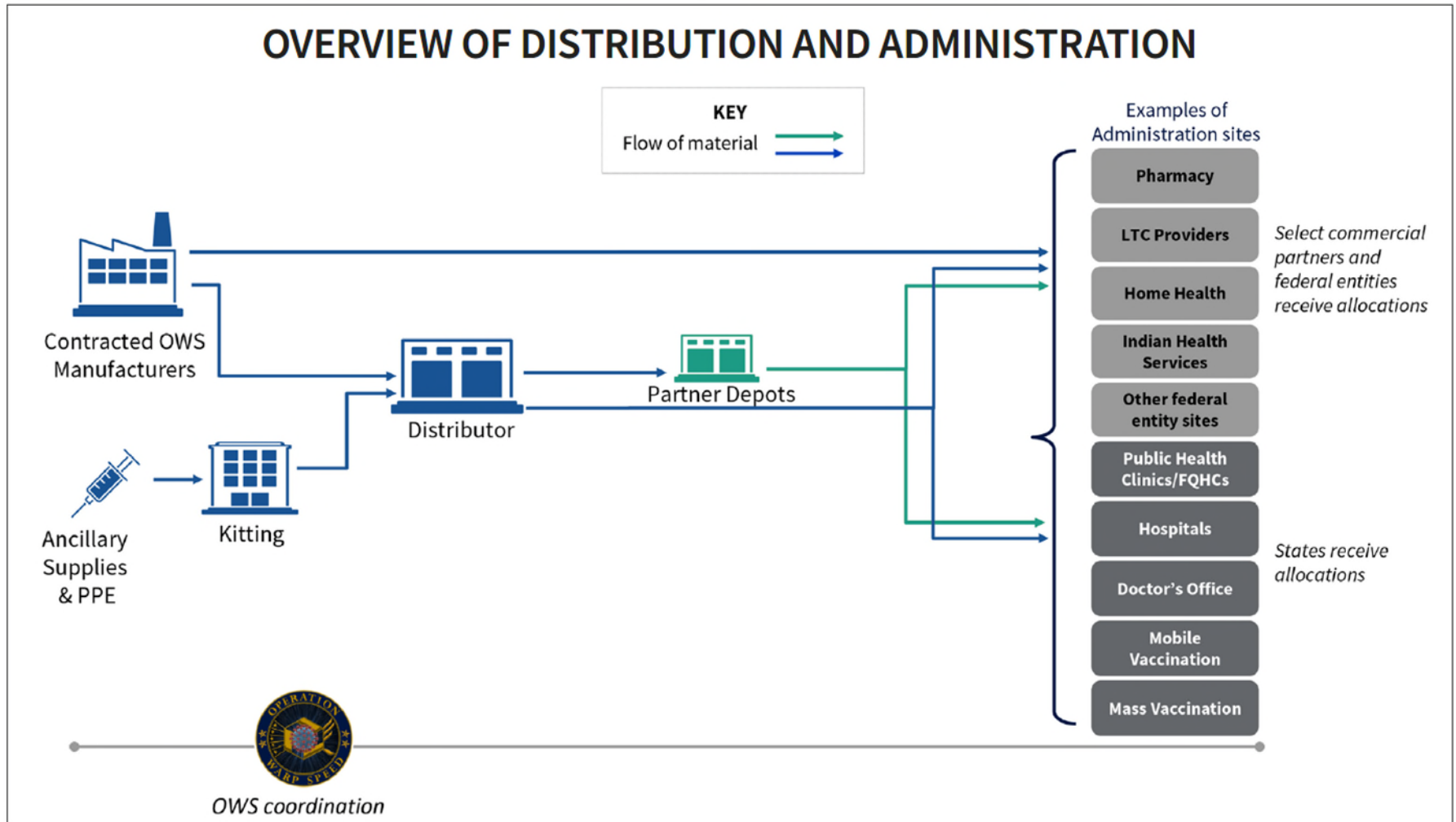
- Experts estimate 70% of U.S. population needs to be vaccinated to achieve herd immunity (*i.e.*, 200 million).
- This could require distribution of 400 million doses, if vaccines require 2 doses.
- H1N1 vaccination reached 81 million.
- CDC has overseen mass vaccination programs in the past, but the White House created Operation Warp Speed (OWS) to facilitate COVID-19 vaccination development and distribution.



CDC Guidance

- Manufacturers will deliver vaccine to centralized distributor (McKesson) for distribution to vaccine administration sites, or deliver vaccine directly (Pfizer)
- Jurisdictions will receive regular allocations based on population
- Allocations will rise over time as more vaccine becomes available
- Vaccine administration sites must enroll with the jurisdiction, which will approve orders against allocations based on prioritization guidelines recommended by CDC
- Jurisdictions are responsible for developing distribution plans and recruiting vaccine administration sites

OWS Guidance



Planning for Vaccine Administration Sites

- Enroll in jurisdiction
- Sign CDC provider agreement
- Ancillary supplies will be provided by federal government
- Ensure dose level accountability and reporting
- Report required data elements within 24 hours
- Ensure that vaccine can be administered in socially distant, safe manner
- Assess ability to ensure cold chain

Planning Assumptions for Sites

- **Planning for Alternative Scenarios**
 - Pfizer –
 - Requires storage at $-70^{\circ}\text{C} \pm 10^{\circ}\text{C}$
 - 2-dose series (21 days between doses).
 - Minimum order of 975 doses.
 - Must be thawed and reconstituted
 - Moderna
 - Requires storage at -20°C
 - 2-dose series (28 days between doses)
 - Minimum order of 100 doses

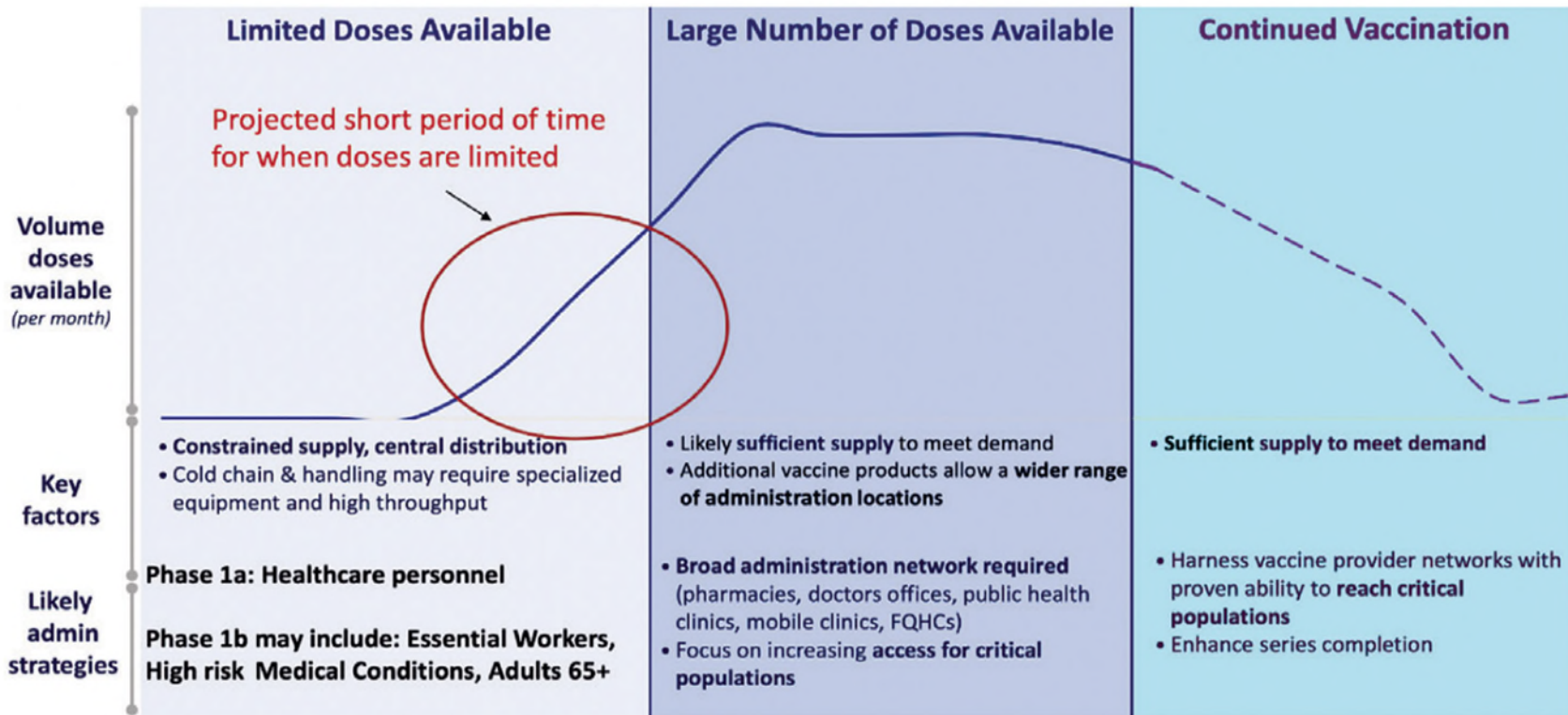


Unanswered Questions

- Will funding be provided to jurisdictions to assist with vaccine distribution?
- Will the technology infrastructure be adequate?
- Can states resolve legal/regulatory issues related to information sharing?
- Will people take the vaccine?

Allocation Phases

FIGURE 1: VACCINE ADMINISTRATION BY PHASE



Source: Adapted from CDC ACIP [Sept 2020](#) and [Dec 2020](#) meeting presentation

ACIP Prioritization Guidelines

FIGURE 2: POTENTIAL PRIORITIZATION OF CRITICAL POPULATIONS ACROSS PHASES

Phase 1*(~261 M+)	Additional Prioritization to Be Determined in Later Phases
Phase 1a <ul style="list-style-type: none">• Health care personnel: ~21 M• Long-term care facility residents: ~3 M	<ul style="list-style-type: none">• Staff and residents of other congregate living facilities• People of all ages with conditions that put them at <i>moderately</i> higher risk• Prisoners, detainees, and staff• Young adults• Children• Everyone residing in the United States who did not have access to the vaccine in previous phases
Phase 1b <ul style="list-style-type: none">• Essential workers (non-healthcare): ~87 M	
Phase 1c <ul style="list-style-type: none">• Adults with high-risk medical conditions: >100 M• Adults ≥ 65 years**: ~50 M	
<p>* CDC ACIP Dec 2020 meeting presentation</p> <p>**Excluding older adults in LTCFs</p>	

Health Equity in Prioritization Guidelines

- How should disproportionate burden of COVID-19 morbidity and mortality among black, indigenous, and other minority populations impact prioritization?
- No explicit guidance from ACIP
- States taking a variety of approaches:
 - North Carolina specifically cited historically marginalized populations as early phase critical population group
 - California developed a composite health equity metric that measures case and positivity rates and uses them to inform vaccination allocation
 - Prioritize equity in all allocation phases based on CDC Social Vulnerability Index

Immunity – The Prep Act, 42 U.S.C. 247d-6d

- Subject to the other provisions of this section, a **covered person** shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a **covered countermeasure** if a **declaration under subsection (b)** has been issued with respect to such countermeasure.
- Relevant declaration is the Declaration for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (March 17, 2020) (and subsequent amendments)

Declaration for Medical Countermeasures Against COVID-19

- Vaccine approved by FDA or under EUA is a covered countermeasure
- Immunity is only available for (i) activities related to a contract, grant or other arrangement with the federal government, and (ii) activities authorized by an “Authority Having Jurisdiction” following a declaration of emergency

“Covered Person”

- A qualified person administering a countermeasure
- “Program planners” - includes a person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a [Declaration of Public Health Emergency]
- An official, agent, or employee of a person or entity described above
- **March 17, 2020 Declaration:** A “Program Planner” includes a private sector employer, community group, or any individual or organization acting in accordance with the PREP Act and Declaration.

Does Immunity Apply to Decisions to Prioritize Certain Individuals in Vaccine Administration?

- *Casabianca v. Mt. Sinai Med. Ctr., Inc.*, 2014 N.Y. Misc. LEXIS 5998 (N.Y. 2014) – PREP Act only applies to administration of a covered countermeasure, not to decision not to administer a covered countermeasure.
- But, Fourth Amendment to Declaration for Covered Countermeasures (Dec. 9, 2020) -
 - *Not* administering a Covered Countermeasure to one individual in order to administer the Covered Countermeasure to another individual, when supplies are limited, can fall within scope of immunity, particularly when done in accordance with a public health authority's directive

Immunity

The Prep Act, 42 U.S.C. 247d-6d

- **Limitations to immunity:**
 - Federal cause of action for “willful misconduct” causing death or serious injury filed in the District of Columbia.
 - Federal enforcement actions against manufacturers/distributors
 - Claims under federal law for equitable relief
- Otherwise, compensation for serious injury or death may only be obtained from the Covered Countermeasure Process Fund.
- **PREP Act Immunity does not eliminate need for appropriate insurance and risk management.**

Andrea M. Kirshenbaum

Chair, Wage and Hour Practice Group
Principal, Employment and Employee Relations Practice Group
Member, COVID-19 Taskforce
Post & Schell, P.C.

akirshenbaum@postschell.com

(215) 587-1126



Elizabeth M. Hein

Associate, Health Care Practice Group
Member, COVID-19 Taskforce
Post & Schell, P.C.

ehhein@postschell.com

(215) 587-1075

